

**Proposed Amendment of
10A NCAC 26F .0105 and .0106
Schedule of Controlled Substances**

Agency: DHHS/ Division of Mental Health, Developmental Disabilities and Substance Abuse Services

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Statutory Authority: G.S. 90-88(d)

Summary of Impact:

Federal Impact:	None
State Impact:	None
Local Impact:	None
Substantial Economic Impact:	No

I. Overview

It is proposed that the Schedule IV and Schedule V rules be amended to include the following substances that have been added and classified by the Federal Department of Health and Human Services as follows:

- Carisoprodol added as a depressant in Schedule IV, and
- Ezogabine, in any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts in Schedule V (see proposed text in the Appendix).

The federal government issued the final rule for Carisoprodol in December, with an effective date of January 11, 2012. The final rule for Ezogabine was issued December 15, 2011 and became effective the same day. Neither drug is scheduled at this time in North Carolina.

Pursuant to N.C.G.S. § 90-88(d), "If any substance is designated, rescheduled or deleted as a controlled substance under federal law, the Commission shall similarly control or cease control of, the substance under this Article unless the Commission objects to such inclusion. The Commission, at its next regularly scheduled meeting that takes place 30 days after publication in the Federal Register of a final order scheduling a substance, shall determine either to adopt a rule to similarly control the substance under this Article or to object to such action. No rule-making notice or hearing as specified by Chapter 150B of the General Statutes is required if the Commission makes a decision to similarly control a substance."

The Commission, at its February 23, 2012 meeting, elected to similarly schedule these substances.

II. Rationale for Proposed Rule

The Commission for MH/DD/SAS has authority to schedule substances, including express authority to amend the schedules to conform with federal law. Formally amending the rules will maintain consistency with federal DHHS scheduling.

III. Analysis of Fiscal Impact

Both Carisoprodol and Ezogabine, in any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, have already been classified by the federal government and are federally scheduled. Accordingly, all record keeping, storage, and other procedures under the Federal Controlled Substances Act are already required. The rule amendment simply references the federal rules and indicates they must be followed. Facilities dispensing these substances would not incur any additional costs or burden from this action. The Division does not anticipate increased volume or length of inspections as facilities would also be dispensing other controlled substances.

Therefore there is no fiscal impact resulting from the scheduling of these substances.

APPENDIX

10A NCAC 26F .0105 SCHEDULE IV

(a) Schedule IV shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name or brand name designated and as specified in G.S. 90-92. Each drug or substance has been assigned the Drug Enforcement Administration controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.14.

(b) The Commission for MH/DD/SAS may add, delete or reschedule substances within Schedules I-VI as specified in G.S. 90-88.

(c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substances within Schedule IV for Depressants:

- (1) Dichloralphenazone;
- (2) Zopiclone; ~~and~~
- (3) ~~Fosporopol~~; Fosporopol; and
- (4) Carisoprodol

History Note: Authority G.S. 90-88; 90-92; 143B-147;
Eff. June 30, 1978;
Amended Eff. July 1, 1993; January 1, 1989; December 1, 1987; August 1, 1987;
Temporary Amendment Eff. May 28, 1998;
Temporary Amendment Expired March 12, 1999;
Amended Eff. August 1, 2000;
Temporary Amendment Eff. January 1, 2002; February 15, 2001;
Amended Eff. July 1, 2011; November 1, 2005; April 1, 2003; August 1, 2002.

10A NCAC 26F .0106 SCHEDULE V

(a) Schedule V shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name or brand name designated, listed in this Rule.

(b) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

- (1) not more than 200 milligrams of codeine per 100 milliliters or per 100 grams,
- (2) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams,
- (3) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams,
- (4) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit,
- (5) not more than 100 milligrams of opium per 100 milliliters or per 100 grams,
- (6) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms atropine sulfate per dosage unit.

(c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers: Pyrovalerone - 1485.

(d) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts: ~~Lacosamide~~.

- (1) Lacosamide; and
- (2) Ezogabine.

History Note: Authority G.S. 90-88; 90-93; 143B-147;
Eff. June 30, 1978;
Amended Eff. February 1, 2010; April 1, 1992; August 1, 1988; December 1, 1987; April 1, 1983.